



Atty. Dkt. No. 030481-0214

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Gunnar ÅSTRÖM
Title: GRID FOR GUIDED OPERATIONS
Appl. No.: 10/777,223
Filing Date: 02/13/2004
Examiner: Tania C. Courson
Art Unit: 2859

CLAIM FOR CONVENTION PRIORITY

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

The benefit of the filing date of the following prior foreign application filed in the following foreign country is hereby requested, and the right of priority provided in 35 U.S.C. § 119 is hereby claimed.

In support of this claim, filed herewith is a certified copy of said original foreign application:

- SWEDEN Patent Application No. 0301977-5 filed 07/03/2003.

Respectfully submitted,

Date May 5, 2005

FOLEY & LARDNER LLP
Customer Number: 22428
Telephone: (202) 672-5426
Facsimile: (202) 672-5399

By 

Glenn Law
Attorney for Applicant
Registration No. 34,371

PRV

PATENT- OCH REGISTRERINGSVERKET
Patentavdelningen

Intyg Certificate



Härmed intygas att bifogade kopior överensstämmer med de handlingar som ursprungligen ingivits till Patent- och registreringsverket i nedannämnda ansökan.

This is to certify that the annexed is a true copy of the documents as originally filed with the Patent- and Registration Office in connection with the following patent application.

(71) Sökande Radi Medical Systems AB, Uppsala SE
Applicant (s)

(21) Patentansökningsnummer 0301977-5
Patent application number

(86) Ingivningsdatum 2003-07-03
Date of filing

Stockholm, 2005-03-30

För Patent- och registreringsverket
For the Patent- and Registration Office


Hjordis Segerlund

Avgift
Fee 170:-

Field of the invention

- 5 The present invention relates generally to a medical guidance device for use in CT-guided medical operations, and in particular to a grid with which the correct entrance position for a biopsy instrument can be determined during a CT-guided biopsy operation.

10

Background of the invention

- 15 In a medical operation involving the percutaneous insertion of an elongated instrument to a predetermined position within a patient's body, the direction and the insertion depth as well as the entrance position at the patient's skin have to be determined. When the medical operation in question is a biopsy operation performed by means of computerized tomography (CT), the direction and the insertion depth can be calculated from coordinates given on a CT screen. Regarding the entrance position, a CT scanner provides information about where a particular picture of a slice has been taken, i.e. the position along the length of patient's body is known, but the position transverse to the body extension is unknown. Apparently, both a transverse coordinate and a longitudinal coordinate are needed to determine a correct entry point. To facilitate the establishment of the correct entry point at the skin surface, some kind of grid can be arranged on the skin at the approximated entry area.

25

- In its simplest form, such a grid may consist of a number of catheters or similar items that the medical personnel attach on the skin surface. A more dedicated grid has, however, previously been proposed by the present applicant. This grid consisted essentially of a generally rectangular frame, with a number of transverse grid bars extending between the long sides of the rectangular frame. The grid was intended and designed for use together with a special CT-guidance device, and its construction regarding versatility and user-friendliness can be improved.

30

Summary of the invention

35

- 40 As mentioned above, the previously known grid was designed to be used in combination with a special CT-guided biopsy device. The construction of this CT guide did not allow the removal of the grid over an instrument, such as a biopsy needle, introduced in a patient's body. Consequently, the grid was not designed to be removable and repositionable. It has now, however, been realized that it is advantageous to be able to remove and reposition a grid during a biopsy operation. It has further been recognized that during, for example, a biopsy operation, there can be a need for extra palpation of the area under which the tissue of interest is disposed.

45

- 50 The object of the present invention is to provide an improved grid comprising a flat frame provided with transverse ribs or bars, the improvement being that the transverse ribs are elastic such that two adjacent ribs can be stretched and separated from each other. An opening is thereby created, by which the grid can be threaded over a biopsy instrument introduced between the two ribs. With a grid having elastic ribs, it is also

possible to palpate the area below the grid without removing the grid, something that can be of considerable advantage when the grid is attached to a patient's skin by, for example, adhesive tape or adhesive provided at the underside of the grid.

- 5 Furthermore, when determining between which two grid ribs a percutaneous operation is to be performed, a doctor must decide if the respective ordinal number of a rib is counted from the left or right side of the grid. A grid should therefore preferably be equipped with some kind of markings that enable a doctor to unambiguously distinguish the right side of the grid from the left side. A distinguishing feature of this
10 kind is even more valuable when the grid is a removable and repositionable grid – as provided by the present invention – because the risk of accidentally rotating the grid 180° during repositioning of the grid should be eliminated. In one embodiment of the present invention, one of the sides of the grid frame is therefore provided with an enlarged width in comparison with the opposite side, whereby the risk of accidentally
15 rotating the grid 180° is avoided.

Brief description of the drawings

- 20 Fig. 1 shows a grid according to the present invention in an unstretched state.
- Fig. 2 is a schematic illustration of how the grid of Fig. 1 is used in a biopsy operation.
- 25 Fig. 3 shows the grid of Fig. 1 in a stretched state.

Detailed description of the preferred embodiment

- 30 In Fig. 1, a grid 10 according to the present invention is illustrated. The grid 10 comprises a generally flat and rectangular frame having two long sides 11a, 11b and two short sides 12a, 12b. Several transverse bars or ribs 13, 14 are connected to the long sides 11a, 11b. To strengthen the frame and to facilitate the determination of between which of the ribs a puncture is to be performed, some of the ribs have been
35 given a larger width than the other ribs. As can be seen from Fig. 1, each fifth rib is broader than the intermediate ribs. These broader ribs have been marked with reference numeral 14, and the frame is also provided with numbers (in this example, 0, 5, 10 and 20) that represent the ordinal number of the respective rib. It should further be noted that one of the short sides (short side 12a in Fig. 1) has been given a
40 larger width than the opposite short side 12b. The purpose and advantage of the latter feature will become apparent from the description below.

- Fig. 2 is a schematic illustration of a picture of a slice that can be obtained by a CT scanner during a medical operation in which the grid 10 described above is used. The
45 grid 10 of Fig. 1 has been arranged on a patient's skin 18. From the CT scanned slice it has been determined that the puncture should be performed between the fourth and fifth ribs of the grid 10, when counted from the short side 12a having the larger width. As can be seen from Fig. 2, a biopsy needle 15 has been introduced in the patient's body tissue 16, such that the distal end of the biopsy needle 15 is positioned within
50 target tissue 17, while the proximal end of the biopsy needle 15 extends out of the

patient's skin 18. Here it should be noted that the grid 10 preferably is made from a radiopaque material, so that the grid ribs appear clearly on a CT-scanned slice. If the operation instead is performed by means of magnetic resonance (MR) tomography or positron emission tomography (PET), other suitable materials may be considered.

5 Instead of having a side with a larger width than the opposite side, one of the sides could be provided with another type of distinguishing feature, e.g. a recess or other formation, or one side could be made from a material that on a CT screen appears differently from the material in the opposite side.

10 As mentioned above, it has now been realized that it can be desirable to remove a grid, with a medical instrument such as a biopsy needle still in place. For this purpose, the ribs of a grid according to the invention are designed to be elastic, such that the grid can be threaded over the biopsy needle. Fig 3 illustrates how an opening is created in the grid 10 of Fig. 1. As illustrated in Fig. 3, by using his or her fingers a
15 doctor or other medical personnel can separate two neighbouring ribs 13 such that an opening is provided. Without touching a biopsy instrument inserted between two ribs and thereby affecting its position, a doctor can therefore thread the grid 10 over a biopsy instrument that remains inserted into a patient's body. The underside of a grid according to the invention may be provided with an adhesive which allows the grid to
20 be fixated to a patient's skin. To still have a removable grid, such an adhesive should be a releasable adhesive. Furthermore, the adhesive should preferably only be provided at the frame of the grid such that the grid ribs can be separated from each other.

25 One particular reason for removing a grid during a biopsy operation can be that further palpation is required, such that a doctor needs access to the skin area around the biopsy instrument to palpate underlying structures, e.g. bones, ribs or vessels, in order to perform a biopsy operation close to or between bones, and minimizing the risk of hitting susceptible structures with a biopsy needle. In this respect, the grid
30 according to the present invention provides a further advantage. As may be appreciated from Fig. 3, palpation on the skin area surrounding a biopsy instrument can, at least in some cases, actually be carried out without removing the grid. That is, by stretching and separating the ribs such that an opening is created in the grid, a doctor acquires free access to a skin area at which palpation, or some other type of
35 medical procedure, can be performed.

Although the present invention has been described with reference to a specific embodiment, also shown in the appended drawings, it will be apparent for those skilled in the art that many variations and modifications can be done within the scope
40 of the invention as described in the specification and defined with reference to the following claims. For example, although a rectangular shape of the grid frame is presently regarded as the preferred embodiment of the invention, other shapes are within the scope of the invention. The grid frame could be quadratic (which is consider as a special case of a rectangular grid), triangular, or rhombic, or the grid
45 frame could have more than four sides, including a circular shape. Further, some of these ribs, e.g. the ribs having a larger width, could be made from a less elastic or even non-elastic material, as long as it is possible to separate adjacent ribs enough to create an opening in the grid.

50

Claims

1. Grid (10) adapted to be arranged on a patient's skin to provide positioning information in a CT-guided percutaneous operation, comprising a frame within which several ribs (13, 14) are arranged, **characterized in** that at least some of the ribs (13, 14) are elastic.
2. Grid (10) according to claim 1, **characterized in** that some of said several ribs (14) are broader, with a regular number of narrower ribs (13) arranged therebetween.
3. Grid (10) according to claim 1 or claim 2, **characterized in** that the grid (10) is rectangular with two long sides (11a, 11b), between which said several ribs (13, 14) are connected, and two short sides (12a, 12b), of which one (12a) is distinguishably different from the other (12b).
4. Grid (10) according to anyone of the claim 3, **characterized in** that one short side (12a) is broader than the opposite short side (12b).
5. Grid (10) according to anyone of the claims 1 to 4, **characterized in** that the grid (10) is provided with markings that show the ordinal number of the respective rib (13, 14).
6. Grid (10) according to anyone of the claims 1 to 5, **characterized in** that the grid is radiopaque.
7. Grid (10) according to anyone of the claims 1 to 5, **characterized in** that the grid (10) is made from a material that is visible in a magnetic resonance tomograph.
8. Grid (10) according to anyone of the claims 1 to 5, **characterized in** that the grid (10) is made from a material that is visible in a positron emission tomograph.
9. Grid (10) according to anyone of the claims 1 to 8, **characterized in** that the underside of the grid (10) at least partly is provided with an adhesive.
10. Grid (10) according to claim 9, **characterized in** that the underside of the frame is provided with an adhesive.

Abstract

The invention relates to a grid (10) adapted to be arranged on a patient's skin to provide positioning information in CT-guided percutaneous operations. In one embodiment, the grid (10) comprises a flat and generally rectangular frame having two long sides (11a, 11b) and two short sides (12a, 12b), with a number transverse ribs (13, 14) being provided between the two long sides (11a, 11b). According to the invention, at least some of the transverse ribs (13, 14) are elastic. By using his/her fingers, a doctor can thereby separate two neighbouring ribs (13, 14) such that an opening is provided in the grid (10). Through this opening access is obtained to the skin area under the grid (10), or the grid (10) can be threaded over and removed from a medical instrument which, between two adjacent ribs (13, 14), is inserted into the patient's body.

00407-03

